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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,087	11/20/2001	Stephen G. Sligar	87-00	1280

23713 7590 12/02/2003

GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/990,087	SLIGAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ruixiang Li	1646	

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/11/2003.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 20-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10 and 13 is/are rejected.
- 7) ☒ Claim(s) 8 and 14-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                             | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9032003</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendments filed on September 3, 2003 and September 11, 2003 have been entered in full. Claims 1-9, 19, 20, 27, 34, and 36 have been amended. Claims 29-33 have been canceled. Claims 1-28 and 34-36 are pending. Claims 1-10 and 13-19 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Restriction/Election**

Applicants continue to argue about the restriction/election requirement set forth in the record. The Examiner noted that this restriction/election requirement has been made final in the previous Office action (Paper No. 8, June 11, 2003) and is no longer arguable.

### **III. Request for Corrected filing Receipt**

Applicants' request for Corrected Filing Receipt filed on October 3, 2003 has been granted. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

#### **IV. Information Disclosure Statement**

The Information Disclosure Statement filed on September 3, 2003 has been received by the Office and the references listed in Form PTO-1449 have been considered by the Examiner.

#### **V. Withdrawn Objections and/or Rejections**

The rejection of claims 1-7 and 9 under 35 U.S.C. §101, as set forth at page 4 in the previous office action (Paper No. 8, June 11, 2003) has been withdrawn in view of Applicants' amendment to the claims.

The objection of claims 1 and 4 for minor informalities, as set forth at page 5 in the previous office action (Paper No. 8, June 11, 2003) has been withdrawn in view of Applicants' amendment to the claims.

#### **VI. Claim Rejections under 35 USC § 102 (b)**

(i) The rejection of claims 1-7, 9, 10, and 13 under 35 U.S.C. §102 (b) as being anticipated by Bayburt et al., as set forth at page 5 in the previous office action (Paper No. 8, June 11, 2003) remains.

Applicants argue that the claims have been amended to recite an "artificial" membrane scaffold protein, whereas artificial membrane scaffold proteins are distinct from apolipoprotein AI in their amino acid sequences.

Applicants' argument has been fully considered, but is not deemed to be persuasive because a membrane scaffold protein, e.g., apo A-I protein, can be made by

DNA recombinant technology and such an artificial scaffold protein can have the same sequence as that of a membrane scaffold protein isolated from a natural source. Since the specification fails to unambiguously define an artificial scaffold membrane protein as one that has distinct amino acid sequence from a naturally occurring scaffold membrane protein, the word “artificial” does not limit the scope the claimed invention. Thus, the reference of Bayburt et al. still reads on the limitations of claims 1-7, 9, 10, and 13.

(ii) Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Frank et al. (Biochemistry, 36:1798-1806, 1997).

Frank et al. teach a recombinant wild-type human apoA-I (His-apoA-I) expressed in *E. coli* with an N-terminal extension of 11 residues (Met-Arg-Gly-Ser-(His)<sub>6</sub>-Met), and three apoA-I mutants. Frank et al. teach that the His-apoA-I exhibits similar physicochemical properties to native apoA-I and can form homogeneous discoidal apoA-I-containing lipoproteins with phospholipids, which exhibit sizes ranging from 9.5 to 10.5 nm. The three mutants also demonstrate a property forming homogeneous discoidal apoA-I-containing lipoproteins in a slightly smaller size (See, e.g., Abstract).

Furthermore, the membrane scaffold proteins taught by Frank et al., which are either native or artificial, would, by their nature, form a nanoscale particle with at least one hydrophobic or partially hydrophobic protein as recited in claim 4. The membrane scaffold proteins would also form a nanoscale particle as recited in claims 5-7 in the presence of amphipathic lipid molecules (e.g., cholesterol, and glycolipids) other than

phospholipids. Therefore, the reference of Frank et al. meets the limitations of claims 1-7.

## **VII. Claim Objections**

Claims 8, 18, and 19 remains objected to because they recite unelected subject matter, amino acid sequences (SEQ ID NOS: 6, 9, 19, 23, 29, 43-45).

Claims 14-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

## **VIII. Prior Art**

The following prior art made of record in PTO-1449 (i-iv) or in PTO-892 (v-vi) and not relied upon is considered pertinent to applicant's disclosure.

- (i) Koppaka et al., *J. Biol. Chem.* 274: 14541-14544, 1999.
- (ii) Borhani et al., *Proc. Natl. Acad. Sci. USA* 94:12291-12296, 1997.
- (iii) Rogers et al., *Biochemistry* 37: 945-955, 1998
- (iv) Rogers et al., *Biochemistry* 37: 11714-11725, 1998
- (v) Bergeron et al., *Biochim Biophys Acta* 1344:139-152, 1997.
- (vi) Bergeron et al., *J. Biol. Chem.* 270 : 27429-27438, 1995.

## **IX. Conclusion**

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
November 24, 2003

  
YVONNE EYLER, PH.D.  
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TECHNOLOGY CENTER 1600